K062202
p. 1 of 1

510(k) Summary

OCT 20 2006

General Provisions	**Trade Name**: To be determined **Classification Name:** Percutaneous Catheter
Name of Predicate Devices	Occlusion Balloon Catheter, Van-Tec Occlusion Balloon Catheter
Classification	Class II
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.
Intended Use	Occlusion Balloon Catheters are indicated for use for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures. The Occlusion Balloon Catheter product line consists of two specific designs – Standard Occlusion Balloons and Berenstein™ Occlusion Balloon Catheters. Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.
Device Description	The proposed devices are constructed of a dual lumen catheter shaft to which two luer fittings are attached proximately and a soft compliant balloon is mounted on the distal end of the shaft. The tubing marked BALLOON is the balloon inflation lumen. The tubing marked DISTAL is the central lumen. The central lumen is used to pass the catheter over a guidewire. This lumen can also be used for infusion of contrast medium or, in the case of the Berenstein Occlusion Balloon Catheter, coaxial delivery of small catheters or embolic agents. As are the predicated devices, the proposed devices are provided with 1.25ml syringe. There are no changes to this accessory proposed in this submission
Biocompatibility	Occlusion Balloon Catheters have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.
Summary of Substantial Equivalence	Occlusion Balloon Catheters have been tested and compared to the predicate devices. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2006

Boston Scientific Corporation
c/o Mr. Nicholas Condakes
100 Boston Scientific Way
Marlborough, MA 01752

Re: K062202
Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: September 26, 2006
Received: September 27, 2006

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062202

Indications For Use

510(k) Number (if known) ~~Unknown~~ K062202

Device Name: Occlusion Balloon Catheter

Indications for Use

Occlusion Balloon Catheters are indicated for use for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.

The Occlusion Balloon Catheter product line consists of two specific designs – Standard Occlusion Balloons and Berenstein™ Occlusion Balloon Catheters.

Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062202